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REMARKS

Claims 1-20 are pending in this application. The Examiner contends that this Application contains the following inventions or groups of inventions:

Group I, claims 1-4, 9-12 and 16-20, drawn to multiple inducible gene modulation systems.

Group II, claims 5 and 13, drawn to a transgenic organism.

The Examiner suggested that the inventions listed as Groups I and II are distinct as a transgenic organism is a much more complicated system from that of a cell and would have different uses from that of the cell.

Furthermore, the Examiner indicated that claims 1-20 are generic to a plurality of disclosed patentably distinct species of multiple inducible gene modulation systems, comprising ligand binding domain, DNA binding domain, and transactivation domain, and applicant is thus required under 35 U.S.C. § 121 to elect a single disclosed multiple inducible gene modulation system for examination purposes.

In reply, and solely to be responsive to the Examiner's requirement, Applicants provisionally elect Group I, claims 1-4, 9-12 and 16-20, drawn to multiple inducible gene modulation systems comprising ligand binding domain of nuclear receptors; DNA binding domain (DBD) selected from the group consisting of synthetic DBD, chimeric DBD, GAL4 DBD, LexA DBD, transcription factor DBD, Group H nuclear receptor member DBD, steroid/thyroid hormone nuclear receptor superfamily member DBD, and bacterial LacZ DBD; and transactivation domain (AD) selected from the group consisting of Group H nuclear receptor member AD, steroid/thyroid hormone nuclear receptor superfamily member DBD, synthetic AD, chimeric AD, polyglutamine AD, basic amino acid AD, acidic amino acid AD, VP16 AD, GAL4 AD, NF-κB AD, BP64 AD, B42 acidic activation domain (B42AD), and p65 transactivation domain (p65AD), with traverse.

Under 35 U.S.C. § 121, restriction may be required if "two or more independent and distinct inventions are claimed in one application." According to the interpretation provided in MPEP § 802.01, the term "independent" means that "there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect...." The term "distinct" is defined in MPEP § 801.02 as meaning that "two or more subjects as disclosed are related... but are capable of

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separate manufacture, use or sale as claimed, and ARE PATENTABLE (novel and unobvious) OVER EACH OTHER..." (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

The above-cited language of 35 U.S.C. § 121 is clear in that the requirement to restrict an application to one of the inventions disclosed therein is proper only if the disclosed inventions are both independent and distinct. While Applicants take no position on the patentable distinctness of the multiple inducible gene modulation systems, comprising ligand binding domain, DNA binding domain, and transactivation domain of Group I, Applicants submit that the multiple inducible gene modulation systems of Group I are not independent and are so linked as to form a single general inventive concept, which is multiple inducible gene regulation. The inventive concept requires a plurality of inducible gene expression systems. The examples provided in the specification of the instant application demonstrate that multiple ligand binding domains, DNA binding domains, and activation domains are used to create multiple inducible gene regulation systems that are orthogonal. This is the invention.

The lengthy explanation provided in MPEP § 802.01 of why restriction can be properly required among independent or distinct inventions is in contradiction to the plain language of the statute and the related rules (37 C.F.R. § 1.142). Accordingly, a restriction based upon the alternative use of these terms is questionable. However, even if one accepts the MPEP's interpretation of 35 U.S.C. § 121, the mere existence of two or more independent or distinct inventions in one application is not sufficient to justify a restriction requirement.

According to the guidelines in MPEP § 803, if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

Applicants respectfully submit that prosecution of the multiple inducible gene modulation systems, comprising ligand binding domains, DNA binding domains, and transactivation domains, of Group I in the present application is appropriate. Under Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP

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803, Rev. 8, May 1988) (emphasis added). The plurality of multiple inducible gene modulation systems, comprising ligand binding domain, DNA binding domain, and transactivation domain, designated by the Examiner fail to define products with properties so distinct as to warrant separate examination and search.

Accordingly, examination of the plurality of inducible gene modulation systems of the present claims involves a fundamental determination of the novelty of multiple inducible gene regulation systems. To the extent that this determination would be made, it is submitted that a preponderantly coextensive search would result. In particular, an exhaustive search for one gene modulation system comprising a DNA binding domain, ligand binding domain, and transactivation domain would encompass other inducible gene modulation systems comprising a DNA binding domain, ligand binding domain and transactivation domain.

Thus, Applicants submit that the search and examination of the plurality of multiple inducible gene regulation systems of the present application can be made without serious burden. Applicants respectfully submit that conjoint examination and inclusion of all of the multiple inducible gene regulation systems of the present application would not present an undue burden on the Examiner, and accordingly, withdrawal of this restriction is believed to be in order.

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Conclusion

Applicants respectfully submit that claims 1-20 are drawn to a single general inventive concept as defined in 37 CFR § 1.1. Thus, the plurality of inducible gene regulation systems of Group I as hereinabove defined, are not independent, and although they might be classified in different classes for searching purposes, the search of the claims of these groups does not impose an undue search burden on the Examiner.

Applicants submit respectfully that the Examiner has provided insufficient reasons in support of a restriction between the plurality of inducible gene regulation systems of Group I. In view of the above remarks, Applicants respectfully request reconsideration and withdrawal of this restriction. In the event that the restriction requirement is maintained, Applicants reserve the right to file divisional applications directed to the subject matter of the non-elected claims of Group II and additional multiple inducible gene regulation systems. If a telephone interview would be of assistance in advancing prosecution of this application, Applicants' agent invites the Examiner to contact her at (610) 650-8734 ext. 104.

Respectfully submitted,

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